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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,639	10/27/2003	Michael Cima	TPI-T2200XC2	5317
22913 7590 01/10/2007 WORKMAN NYDEGGER (F/K/A WORKMAN NYDEGGER & SEELEY) 60 EAST SOUTH TEMPLE 1000 EAGLE GATE TOWER SALT LAKE CITY, UT 84111			EXAMINER BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/694,639	Applicant(s) CIMA ET AL.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/05, 1/05, 3/05, 7/05, 5/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 9/27/2004; 1/27/2005; 3/11/2005; 7/25/2005; and 5/8/2006 have been considered and made of record.

Specification

2. The disclosure is objected to because of the following informalities: On page 7, line 30, "Figure 9B" should be --Figure 8B--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 13, 14 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 13 and 14, "said forming" lacks antecedent basis.

In claim 16, line 4, "the assay plate" lacks antecedent basis. Also, how can an array of samples be prepared when the claim only requires "at least one raised pad"?

Claim Rejections - 35 USC § 102

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Monks et al.(US 6,022,700).

With respect to claim 1, the reference of Monks et al. discloses an assay plate including a substrate (20) having a substrate surface (24), at least one raised pad (22) extending from said substrate surface and having a substantially planar sample receiving surface configured for holding a sample thereon (See column 1, line 62, to column 2, line 7, and column 6, lines 47-49).

With respect to claim 2, the raised pad (22) includes at least one sidewall coupling the sample receiving surface to the substrate surface (See column 7, lines 2-4).

With respect to claims 3 and 4, the angle between the sidewall and the sample receiving surface is around 90 degrees (See column 7, line 4).

With respect to claim 5, the assay plate can have a number of different arrays of pads (See column 8, lines 9-25).

With respect to claim 6, the diameter of the pads are around 5mm when provided in an array of 96 pads (See column 7, lines 19-25).

With respect to claim 7, the reference discloses the use of a plurality of raised pads (22).

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With respect to claim 8, the reference employs the disclosed device by depositing a sample in the first end of the raised pad (22) and performs an experiment using the sample on the pad (See column 4, line 30, to column 5, line 44).

7. Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 102(2) as being anticipated by Webb et al.(US 2003/0124029).

With respect to claim 1, the reference of Webb et al. discloses an assay plate including a substrate (10) having a substrate surface (12), at least one raised pad (5) extending from said substrate surface and having a substantially planar sample receiving surface configured for holding a sample thereon (3).

With respect to claim 2, the raised pad (5) includes at least one sidewall coupling the sample receiving surface to the substrate surface (See Figure 2A).

With respect to claims 3 and 4, the angle between the sidewall and the sample receiving surface is around 90 degrees (See Figure 2A).

With respect to claim 7, the reference discloses the use of a plurality of raised pads (5).

With respect to claim 8, the reference employs the disclosed device by depositing a sample in the first end of the raised pad (3) and performs an experiment using the sample on the pad (See Example 1).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 12-15 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monks et al.(US 6,022,700).

The reference of Monks et al. has been discussed above.

With respect to claim 12, while the reference is silent as to whether or not the sample contacted with the first end of the support forms a "raised droplet".

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The reference of Monks et al. discloses that first end of the support member can be “from about 0.5mm to about 5.0mm (See column 7, line 67):

As a result, based on the specific diameter of the support member, the material of the first end and/or the properties of the test sample, one of ordinary skill in the art would recognize that when performing a wet chemistry assay and/or preparing the support ends with sample, the surface tension of the liquid employed relative to the diameter and/or surface properties of the material of construction would form a liquid droplet, if not, the liquid would not be capable of being supported by the end of the support in the absence of a containment sidewall.

With respect to claims 13 and 14, while the reference is silent as to the specific method of manufacturing the device, based merely on the intended size of the support members and/or the intend material to employ, it would have been obvious to one of ordinary skill in the art to determine the optimum manner in which to manufacture the device using any art recognized techniques including, molding, etching, machining, etc. while providing the intended device of a specific material of manufacture including the support members of a desired dimension.

With respect to claim 15, while the reference discloses the use of a first sample (a chemical the enhances attachment (See column 6, lines 53-63)) and the use of tissue sections (See column 3, line 20), the reference does not specifically disclose the combination of the attachment chemical with the tissue section. However, in view of the entire disclosure of the reference, it would have been obvious to one of ordinary skill in the art to employ a chemical to enhance attachment of a tissue to the support member end for the known and expected result of ensuring that the tissue sample remains attached to the end of the support during use.

With respect to claims 19-21, while the exemplified embodiments of the device of Monks et al. is made of glass, the reference discloses that the planar substrate can be made of other materials including polymers and metals (See column 11, lines 63-67), both of which are flexible materials.

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to manufacture the device with a substrate that is flexible for the known and expected result of providing an alternative material of construction as is suggested in the art.

The resulting device would include an array of samples supported on the sample receiving surfaces and can be considered a “transdermal delivery device” in the absence of further positively recited structure.

12. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monks et al.(US 6,022,700) in view of Lichtenwalter (US 2001/0046682).

The reference of Monks et al. has been discussed above.

Claims 9 and 10 differ by reciting that the sample is dried before performing the experiment and/or a second sample is added to the first and dried in a separate step.

The reference of Lichtenwalter discloses that it is known in the art to perform a binding assay wherein a second sample is contacted with a first dried sample. The first sample is dried so as to maintain the first sample in a stabilized form. After contacting the first dried sample with a second sample, the resulting mixture is dried for analysis (See the abstract).

In view of this teaching, it would have been obvious to employ the assay device of the primary reference of Monks et al. in the manner suggested by the reference of Lichtenwalter for

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the known and expected benefits provided of the assay of the reference of Lichtenwalter while providing the structural benefits of the contacting device of the reference of Monks et al.

13. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monks et al.(US 6,022,700) in view of Clayton et al.(US 5,182,216).

The reference of Monks et al. has been discussed above.

Claims 9 and 11 differ by reciting that the sample is dried before performing the experiment and/or the sample is coated on the surface using a plurality of adding and drying steps.

The reference of Clayton et al. discloses that it is known in the art to coat the surface of a solid support of an assay device using a plurality of application and drying steps (See column 6, lines 15-18).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the surface of the device of the primary reference using the method disclosed by the reference of Clayton et al. when employing the device in a solid phase immunoassay the requires a thick coating of reagent.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 16-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-37 of U.S. Patent No. 6,908,760. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 16-18 are generic to all that is recited in claims 34-37 of U.S. Patent No. 6,908,760. That is, claims 34-37 of U.S. Patent No. 6,908,760 fall entirely within the scope of instant claims 16-18 or, in other words, instant claims 16-18 are anticipated by claims 34-37 of U.S. Patent No. 6,908,760.

16. Claims 19-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 94, 95 and 106 of copending Application No. 10/556,996. An obviousness-type double patenting rejection is appropriate where the conflicting

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claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 19-21 are generic to all that is recited in claims 94, 95 and 106 of copending Application No. 10/556,996. That is, claims 94, 95 and 106 of copending Application No. 10/556,996 fall entirely within the scope of instant claims 19-21 or, in other words, instant claims 19-21 are anticipated by claims 94, 95 and 106 of copending Application No. 10/556,996.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

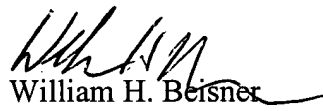
Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB